

## REMARKS

As an initial matter, it is noted with appreciation that claims 19 and 25 are allowable, but objected to as depending from a rejected base claim. Claims 19 and 25 have been amended to be in independent form, and include all of the limitations of the base claims and any intervening claims. Allowance of these claims is requested.

The Examiner has rejected claims 1-18, 20-24 and 26-30 under 35 U.S.C. §103(a) as being unpatentable over U.S. Published Patent Application No. 2002-26110 to Parris et al. in view of U.S. Patent No. 6,303,305 to Wittwer et al. and U.S. Published Patent Application No. 2003-78746 to Samsundar. The Examiner alleges that Parris et al. teach a method of predicting a value of an analyte in a sample at a known time, said method comprising the steps of: making a plurality of observations on a plurality of samples, wherein each observation includes a plurality of variables associated with said samples; generating an equation which approximates said plurality of observations; measuring a sample analyte value, said sample having associated therewith a storage time, and a storage temperature; inputting said storage time and said storage temperature into said equation, and obtaining an estimated analyte value, wherein the difference between said estimated analyte value and said measured analyte value can be used to calibrate said equation.

The Examiner admits that Parris et al. do not teach measuring a sample analyte value, said sample having associated therewith a container type; inputting said container type, together with said storage time, said storage temperature, and said measured analyte value into said equation; and solving said equation to obtain an estimated initial value.

The Examiner cites Wittwer et al. as disclosing a method for quantification of an analyte, and the steps and means of inputting the measured analyte value into a mathematical equation; and solving the equation to obtain an estimated initial analyte value. The Examiner alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Parris et al. with Wittwer et al. to derive an estimated *initial analyte value* from a measured instant analyte value.

The Examiner cites Samsoundar as suggesting the contribution of *container type* in a method for determining the concentration of an analyte in a sample. Further, the Examiner alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the teaching of Samsoundar in the Parris system in order to consider the variability contributed by container type in estimating an initial value in a sample.

Applicants respectfully disagree with the Examiner's assessment of the present claims in view of the cited art. Parris et al. is directed to a predictive-kinetic method for use with data processing of a sensor-generated signal. The Parris et al. system is useful for predicting the *final* value of an analyte or substance in a chemical reaction that asymptotically approaches that final value. While Parris et al. generate a predictive equation like the present invention, the similarities end there. The sensors described in Parris et al. draw a sample from a subject and measure values in real time. Based on the changing values over time, an approximating equation is used to predict a final value. In this manner, the final value is obtained *more quickly* than if the changing signal were allowed to come substantially to a steady state value prior to measurement.

By contrast, the present invention is particularly useful in situations where *real time* testing is unavailable or impractical. Specifically, and without limitation, the present invention is used in situations where a sample is taken and stored for some amount of time before being tested. This situation is common, for example, where a patient may have a sample of blood drawn in a doctor's office, but the sample is sent to a lab for testing. The time frame for storage of the sample may be on the order of several days.

As the Examiner acknowledged, Parris et al. do not teach predicting an *initial* value based on measurements at a later time. The Examiner suggests a combination with Wittwer et al. Applicants submit that one of ordinary skill at the time the invention was made would not be motivated to combine these references. While Parris et al. is a system and method for predicting a *final* value of an analyte, the Examiner suggests that it would have been obvious to combine Parris with Wittwer, which teaches a method of determining an initial value, to arrive at applicants claimed invention.

Wittwer teaches a system for determining an initial value of a substance whose initial concentration is too small to measure. Amplification of the substance is typically used to determine whether the substance is present or not, but in the prior art, while presense could be determined through amplification, concentration could not reliably be determined due to a "leveling off" phenomenon in the amplification process.

Wittwer is directed to a significantly different problem than either the present invention or Parris. Where the present invention and Parris both deal with measuring analytes in measureable quantities, Wittwer overcomes the problem of determining

initial concentration where amplification of the analyte is required prior to measurement. Wittwer in fact teaches away from the present invention by suggesting an amplification process which *complicates* the process of determining analyte concentration. Wittwer would not be of use to one determining *final* value of an analyte, as in Parris, or initial value, as in the present invention, where the concentration is high enough to be measurable.

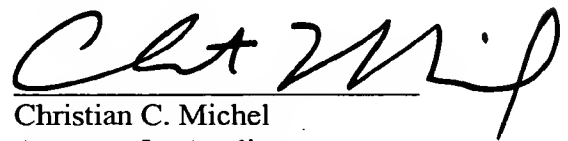
Furthermore, the Examiner has not provided any motivation for the combination of Parris and Wittwer. The mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP §2143.01. Also, the proposed modification can not render the prior art invention unsatisfactory for its intended purpose. *Id.* Parris in fact teaches away from Wittwer by disclosing taking measurements that can include *initial* value measurements. One practicing the Parris invention would have no need for *predicting* initial value, as the direct measurement would be available. The only thing to be gained by Wittwer is the ability to measure initial concentrations so small as to not be measurable directly. Therefore, the Examiner has not established sufficient motivation to make the suggested combination. In view of the above arguments, Applicants respectfully request that the rejection be withdrawn.

In order to clarify that the present invention is directed to systems and methods for predicting initial analyte value where a sample is *stored* for some time prior to being measured, the independent claims have been amended to recite storing the sample for a known non-zero time prior to measuring the analyte value of the tested sample.

Claims 17 and 23 have also been amended for grammatical clarity. In claim 17 the word "level" has been changed to "value" and the word "values" has been changed to "variables." In claim 23 the word "of" has been changed to "if." No change in claim scope is intended by these modifications.

In view of the above arguments and amendments, the claims of the present application are believed to be in condition for allowance. Notice to that effect is respectfully requested. Should the Examiner have any questions, he is invited to contact the undersigned attorney at the number indicated below.

Respectfully submitted,



Christian C. Michel  
Attorney for Applicant  
Reg. No. 46,300

Roylance, Abrams, Berdo & Goodman, L.L.P.  
1300 19<sup>th</sup> Street, N.W., Suite 600  
Washington, D.C. 20036  
(202) 659-9076

Dated: Oct 14, 2003